REMARKS

Allowed and Allowable Claims

The Applicant thanks the Examiner for the indication that claims 16-21 have been allowed. Claim 52 has been objected to, but has been indicated as allowable if rewritten in independent form.

Claim Rejections – 35 USC §102

Claims 15, 22, 23, 39-46, 54, 55, 65 and 67 have been rejected under 35 U.S.C. §102(b) as being anticipated by French Patent No. FR 27003580 to Robert (hereafter "the '580 reference"). Additionally, claims 44, 47-51 and 71 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,599,086 to Doty (hereafter "the '086 reference").

Rejection of Claims 15, 22, 23, 39-46, 54, 55, 65 and 67 Based on the '580 Reference

With regard to the rejection of claims 15, 22, 23, 39-46, 54, 55, 65 and 67 as being anticipated by the '580 reference to Robert, the Applicant fails to understand the basis for these rejections. On page 2 of the Office Action, the following paragraph is the only reference to the subject matter disclosed in the '580 reference to Robert:

> FR 27003580 A1 discloses distraction device (12) comprising an elongate stem (20) having a first end (see Fig. 28), a second end (see Fig. 2), a longitudinal axis, a length along the axis, a flange projection outward (15), and a transverse stop element (15, lower end).

However, the Applicant notes that the '580 reference does not include any of the elements 12, 15 or 20 referred to in the Office Action, nor does the '580 reference include a Figure 28. A copy of the '580 reference is enclosed herewith in Exhibit A.

Based on the Applicant's review of Figures 1 and 2 of the '580 reference (in French), it appears that the '580 reference discloses a tapered interbody implant having a rectangular shape, and a shaft including a pair or prongs that are inserted into a corresponding pair of openings formed in the end wall 5 of the interbody implant. However, the interbody implant does not

include any elements or structures that could be construed as "a flange projection outward" or "a transverse stop element", as referred to in the Office Action.

The Applicant submits that the '580 reference fails to disclose or even suggest the elements and structures referred to in the Office Action. Accordingly, withdrawal of the rejection of claims 15, 22, 23, 39-46, 54, 55, 65 and 67 as being anticipated by the '580 reference is respectfully requested. If the rejection of these claims is maintained, the Applicant requests clarification regarding the basis for such rejections, including reference to the elements or structure shown in Figures 1 and 2 of the '580 reference that correspond to the outwardly projecting flange and the transverse stop element referred to in the Office Action.

Rejection of Claims 44, 47-51 and 71 Based on the '086 Reference

Claims 44, 47-51 and 71 have been rejected as being anticipated by the '086 reference to Doty. As an initial matter, the Applicant notes that claim 51 depends from independent claim 41, which has not been rejected as being anticipated by the '086 reference to Doty. Accordingly, the rejection of dependent claim 51 as being anticipated by the '086 reference appears to be in error.

On page 2 of the Office Action, the basis for the rejections of claims 44, 47-51 and 71 as being anticipated by the '086 reference to Doty is set forth as follows:

> Doty discloses a surgical instrument (32) comprising an elongated stem (12) having a height, a first end, a second end, a longitudinal axis and a flange (66, upper section) extending outward from the stem and a transverse stop element (66, lower end).

It is well established that "an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim." Richardson v. Suzuki Motor Co. Ltd., 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989). The Applicant submits that each of the elements and features recited in the rejected independent claims 44, 48 and 71 is not disclosed in the '086 reference, and respectfully requests withdrawal of the rejection of claims 44, 47-51 and 71 for at least the following reasons.

Independent Claim 44 and Dependent Claims 47, 49 and 50

Independent claim 44 is directed to a distraction device for distracting an intervertebral space and recites, among other elements and features, a stem portion adapted for insertion within the intervertebral space, "a transverse flange portion having a bone contacting face adapted to engage one of the adjacent vertebrae when said stem portion is inserted into the intervertebral space to transmit an axial force to said one of the adjacent vertebrae" and "a transverse stop element . . . adapted to engage an opposite one of the adjacent vertebrae to limit insertion of said stem portion into the intervertebral space".

As an initial matter, independent claim 44 is directed to "a distraction device for distracting an intervertebral space". However, the spinal stabilization device 10 disclosed in the '086 reference comprises an intervertebral prosthesis 12 and a retaining plate 66 which maintains the prosthesis with the intervertebral space. However, there is no teaching or suggestion in the '086 references that the stabilization device 10 distracts the intervertebral space. To the contrary, the '086 reference teaches that the vertebral bodies are initially distracted apart via "conventional distraction devices (not shown)" such that the prosthesis 12 may be subsequently inserted into the intervertebral space. (Col. 3, lines 27-31).

Additionally, the Office Action refers to element prosthesis 12 as comprising an elongated stem, and that the upper portion of the retaining plate 66 defines a flange and the lower portion of the retaining plate 66 defines a transverse stop element. Even assuming arguendo that the proffered characterization of the prosthesis 12 and the retaining plate 66 is proper, the Applicant submits that the top portion of the retaining plate 66 is not "adapted to engage one of the adjacent vertebrae when said stem portion is inserted into the intervertebral space to transmit an axial force to said one of the adjacent vertebrae", as recited in independent claim 44. To the contrary, the '086 reference specifically teaches that the retaining plate 66 is attached to the vertebral bodies 14, 16 "after prosthesis 12 has been positioned between the vertebral bodies 14, 16". (Col. 4, lines 47-52). Accordingly, the upper portion of the retaining plate 66 is not adapted to engage one of the vertebral bodies when the prosthesis 12 is inserted into the intervertebral space to transmit an axial force to the vertebral body, but is instead engaged to the vertebrae subsequent to insertion of the prosthesis 12 into the intervertebral space. Additionally, there is

no teaching or suggestion in the '086 reference that any portion of the retaining plate 66 transmits an axial force to the vertebral body. Instead, the '086 reference teaches that the retaining plate 66 is used to secure the prosthesis 12 in place to prevent posterior migration. (Col. 4, lines 52-53).

The Applicant further submits that the lower portion of the retaining plate 66 is not "adapted to engage an opposite one of the adjacent vertebrae to limit insertion of said stem portion into the intervertebral space", as also recited in independent claim 44. As indicated above, the '086 reference specifically teaches that the retaining plate 66 is attached to the vertebral bodies 14, 16 "after prosthesis 12 has been positioned between the vertebral bodies 14, 16". (Col. 4, lines 47-52). Accordingly, the lower portion of the retaining plate 66 can not fairly be said to be adapted to limit insertion of the prosthesis 12 into the intervertebral space since the '086 references specifically teaches that the retaining plate 66 is engaged to the vertebrae subsequent to insertion of the prosthesis 12 into the intervertebral space.

For at least the reasons set forth above, the Applicant submits that the '086 reference does not teach each and every element and feature recited in independent claim 44. Therefore, the Applicant submits that the rejection of independent claim 44 as being anticipated by the '086 reference is improper, and withdrawal of the rejection of independent claim 44 based on the teachings of the '086 reference is respectfully requested.

Claims 47, 49 and 50 depend from independent claim 44 and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 44. Additionally, further reasons support the patentability of dependent claims 47, 49 and 50. For example, claim 50 recites that "said insertion tool is threadedly engaged with said stem portion". Even assuming arguendo that the wrench 32 comprises an insertion tool, and that the prosthesis 12 comprises a stem portion, the wrench 32 is not "threadedly engaged" with the prosthesis 12. Indeed, the only contact between the wrench 32 and the prosthesis 12 is the engagement of the gear head 34 with the gear teeth 26 on the pins 20. However, the intermeshing engagement between the gear head 34 and the gear teeth 26 clearly does not constitute threading engagement, and the '086 reference fails to even suggest threading engagement between any portion of the wrench 32 and the prosthesis 12.

Independent Claim 48

Independent claim 48 is directed to a distraction device for distracting an intervertebral space and recites, among other elements and features, a stem portion adapted for insertion within the intervertebral space and having a height corresponding to a select distracted height of the intervertebral space, "a transverse flange portion having a bone contacting face adapted to engage one of the adjacent vertebrae when said stem portion is inserted into the intervertebral space to transmit an axial force to said one of the adjacent vertebrae", and an insertion tool engaged with the stem portion and sized to extend outside of the intervertebral space for transmission of the axial force to the adjacent vertebrae, with "said flange portion formed integral with said insertion tool".

The Office Action refers to wrench 32 as comprising a surgical instrument, the prosthesis 12 as comprising an elongate stem 12, and the upper portion of the retaining plate 66 as comprising a transverse flange portion. Even assuming arguendo that the proffered characterization of the wrench 32, the prosthesis 12, and the retaining plate 66 is proper, the Applicant submits that the '086 reference fails to disclose each of the features recited in independent claim 48 for at least the following reasons.

As an initial matter, independent claim 48 is directed to "a distraction device for distracting an intervertebral space". However, as indicated above, the spinal stabilization device 10 disclosed in the '086 reference comprises an intervertebral prosthesis 12 and a retaining plate 66 which maintains the prosthesis with the intervertebral space. However, there is no teaching or suggestion in the '086 references that the stabilization device 10 distracts the intervertebral space. To the contrary, the '086 reference teaches that the vertebral bodies are initially distracted apart via "conventional distraction devices (not shown)" such that the prosthesis may be subsequently inserted into the intervertebral space. (Col. 3, lines 27-31).

Additionally, the top portion of the retaining plate 66 does not comprise a transverse flange portion that is "adapted to engage one of the adjacent vertebrae when said stem portion is inserted into the intervertebral space to transmit an axial force to said one of the adjacent vertebrae", as recited in independent claim 48. To the contrary, as indicated above with regard to independent claim 44, the '086 reference specifically teaches that the retaining plate 66 is

attached to the vertebral bodies 14, 16 "after prosthesis 12 has been positioned between the vertebral bodies 14, 16". (Col. 4, lines 47-52). Accordingly, the upper portion of the retaining plate 66 is not adapted to engage one of the vertebral bodies when the prosthesis 12 is inserted into the intervertebral space to transmit an axial force to the vertebral body, but is instead engaged to the vertebrae subsequent to insertion of the prosthesis 12 into the intervertebral space. Additionally, there is no teaching or suggestion in the '086 reference that any portion of the retaining plate 66 transmits an axial force to the vertebral body. Instead, the '086 reference teaches that the retaining plate 66 is used to secure the prosthesis 12 in place to prevent posterior migration. (Col. 4, lines 52-53).

The Applicant further submits that even assuming arguendo that the wrench 32 comprises a surgical instrument, and that the upper portion of the retaining plate 66 comprises a transverse flange portion, the upper portion of the retaining plate 66 is not "formed integral with" the wrench 32, as recited in independent claim 48. To the contrary, the wrench 32 and the retaining plate 66 comprise individual components that are formed separately from one another. Indeed, as illustrated in Figure 7, the retaining plate 66 defines an opening for passage of the gear head 34 therethrough for engagement with the gear teeth 26 on the pins 20. The wrench 32 does not even appear to come into significant contact with the retaining plate 66, much less being formed integral therewith, as recited in independent claim 48. Moreover, the wrench 32 does not transmit an axial force to a vertebra via a transverse flange portion, as substantially recited in independent claim 48. Instead, the wrench 32 is used to transmit a transverse force to the pins 20 via rotation of the gear head 34. As indicated above, the wrench 32 does not even appear to come into significant contact with the retaining plate 66, much less transmit an axial force to a vertebra via the retaining plate 66.

For at least the reasons set forth above, the Applicant submits that the '086 reference does not teach each and every element and feature recited in independent claim 48. Therefore, the Applicant submits that the rejection of independent claim 48 as being anticipated by the '086 reference is improper, and withdrawal of the rejection of independent claim 48 based on the teachings of the '086 reference is respectfully requested.

Independent Claim 71

Independent claim 71 is directed to a method for performing a surgical procedure on adjacent vertebrae and recites, among other steps and features, providing a device including an axial stem portion and a transverse flange portion, the axial stem portion configured for selective engagement with a surgical instrument, inserting the axial stem portion into an intervertebral space between the adjacent vertebrae, engaging the transverse flange portion against one of the adjacent vertebrae, selectively engaging the surgical instrument with the axial stem portion, with "the surgical instrument comprising a tubular sleeve", and reciting the step of "advancing a surgical device through the tubular sleeve toward the intervertebral space".

The Office Action does not set forth the basis for the rejection of independent method claim 71 as being anticipated by the '086 reference. In particular, there is no indication in the Office Action regarding any disclosure in the '086 reference that teaches the steps of "selectively engaging" a surgical instrument "comprising a tubular sleeve" with an axial stem portion, and "advancing a surgical device through the tubular sleeve toward the intervertebral space". Indeed, the Office Action does not make reference to any element in the '086 patent that corresponds to a tubular sleeve which is engaged to an axial stem portion, nor does the Office Action make reference to an element that corresponds to a surgical device which is advanced through a tubular sleeve. Since there is no basis set forth in the Office Action supporting the rejection of independent claim 71, the Applicant is unable to address such rejection. If the rejection of independent claim 71 as being anticipated by the '086 reference is maintained, it is respectfully requested that the basis for such rejection be communicated to the Applicant.

Additional Comments

The Applicant has addressed each of the rejections set forth in the Office Action. However, as indicated above, the basis for the rejection of claims 15, 22, 23, 39-46, 54, 55, 65 and 67 as being anticipated by the '580 reference to Robert, and the basis for the rejection of independent claim 71 as being anticipated by the '086 reference to Doty, was not clearly set forth in the first Office Action. Additionally, the Applicant has not amended any of the pending claims and has not raised any new issues relating to the patentability. Accordingly, if the

rejection of the claims 15, 22, 23, 39-51, 54, 55, 65, 67 and 71 is maintained, the Applicant submits that the next Office Action can not properly be made final. Additionally, the Applicant invites the Examiner to contact the Applicant's representative at the telephone number set forth below to discuss any remaining issues regarding the subject application in an attempt to further facilitate prosecution of the subject application.

CONCLUSION

In view of the foregoing remarks, it is respectfully submitted that the Applicant's application is in condition for allowance with pending claims 15-22, 23, 39-52, 54, 55, 65, 67 and 71.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

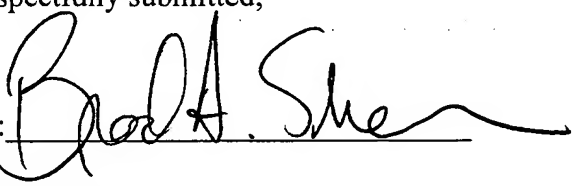
By: 

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EXHIBIT A

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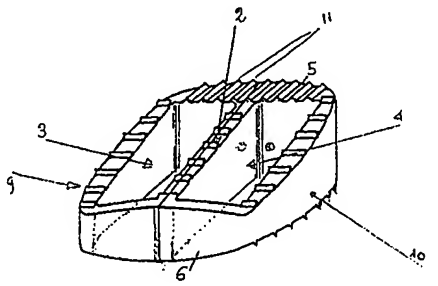
(54) Cage intersomatique cervicale.

(57) L'invention concerne un élément de contention interne et de fusion intersomatique des vertèbres lors de discectomie désigné sous le nom de cage intersomatique.

Les caractéristiques de la cage sont les suivantes:

- Réalisée en polyéthylène ou matériau équivalent résorbable ou non, elle introduit un facteur d'amortissement qui réduit la transmission des contraintes.
- Géométriquement la cage a la forme d'un parallélépipède et peut comporter ou non une cloison médiane de renfort (2). Sa face antérieure (5) et postérieure (6) ont des hauteurs qui sont déterminées pour assurer la conservation d'un espace intervertébral et d'une lordose normale.
- Les arêtes de chacune des faces de la cage sont munies de crans (11) destinés à s'opposer aux déplacements.
- Equipée dans sa partie centrale d'un marqueur radiopaque permettant de suivre, dans le temps, le déplacement de l'implant et permettre la conduite d'examens radiologiques et IRM perturbés.
- Des volumes disponibles pour loger des fragments osseux de dimensions convenables.



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La présente invention concerne une cage de contention, désignée Cage Intersomatique destinée à être insérée entre deux vertèbres. Une telle insertion permet d'étayer l'espace libéré par la discectomie et de procéder à la mise en place d'un greffon osseux destiné à fusionner les deux vertèbres.

Le déroulement de la procédure prévoit les étapes suivantes :

1) Abord de la face antérieure du rachis cervical par incision dans un pli du cou.
2) Incision verticale sur la ligne médiane des muscles prévertébraux et mise en place d'un écarteur autostatique transversal.
3) Repérage radiologique du disque exposé et mise en place de plots vissés au milieu des corps vertébraux sus- et sous-jacents.
4) Distraction vertébrale et discectomie complète. Abrasion des lèvres antérieures des plateaux adjacents.
5) Curetage des plateaux et mise à jour du spongieux sur chaque face intervertébrale pour favoriser la conduction osseuse.
6) Remplissage de la cage à l'aide de deux parallélépipèdes d'os spongieux débordant de 1 mm environ sur les 2 faces.
7) Mise en place de la cage.
8) Ablation de la distraction et fermeture de l'incision.

Les implants métalliques présentent l'inconvénient d'être rigides, donc de transmettre intégralement les contraintes et de constituer, dans certaines conditions, un obstacle à une bonne reconstitution osseuse. De plus, leur poids est élevé et ils provoquent des artefacts au scanner et à l'IRM.
La cage intersomatique, objet de la présente invention, apporte une solution à ces inconvénients.

Les caractéristiques de la cage sont les suivantes :
- Réalisée en polyéthylène ou matériau équivalent résorbable ou non, elle introduit grâce aux propriétés du matériau, un facteur d'amortissement qui réduit la transmission des contraintes.
- Géométriquement la cage a la forme d'un parallélépipède. Elle peut avoir une forme différente et comporter ou non une cloison médiane de renfort (2). Sa face antérieure (5) et postérieure '6) ont des hauteurs qui sont déterminées pour assurer la conservation d'un espace intervertébral et d'une lordose normale.

- Les arêtes de chacune des faces de la cage sont munies de crans (11) destinés à s'opposer aux déplacements.
-Equipée dans sa partie centrale d'un marqueur radiopaque permettant de suivre, dans le temps, le déplacement de l'implant et permettre la conduite d'examens radiologiques et IRM perturbés.
- Des volumes disponibles pour loger des fragments osseux de dimensions convenables permettant la communication osseuse ininterrompue entre la vertèbre sus et sous-jacente amenant par là la fusion intersomatique.

La cage intersomatique est caractérisée dans notre cas, par une géométrie particulière illustrée sur la planche 1/1 mais qui n'est pas limitative et d'autre part en ce que l'usage de matériau plastique, polyéthylène par exemple, est prévu pour sa réalisation. D'autres matériaux, résorbables ou non, présentant des caractéristiques équivalentes peuvent être envisagés. Ce matériau assure une bonne tenue mécanique de la cage tout en introduisant un effet amortisseur qui amoindrit la gène.

En emprisonnant de l'os spongieux, la cage favorise la fusion osseuse d'une manière permanente. Ceci par opposition aux insertions libres de partie d'os qui n'étant pas retenues in situ, auraient tendance, de ce fait, à migrer et induire un déséquilibre entre les faces des corps vertébraux.

La figure 1 illustre les caractéristiques géométriques mais non limitatives de la cage. Celle-ci est constituée par un parallélépipède irrégulier (1) comportant une cloison médiane (2) servant de renfort. Cette cloison dans ce cas détermine deux logements (3) et (4).
Chaque logement sera équipé d'un greffon osseux au moment de la mise en place. La cage peut avoir une surface différente pour le logement d'os, des séparations ou être alvéolée.
La hauteur de la face postérieure (6) est suffisante pour permettre la conservation d'une hauteur cervicale normale. Celle de la face antérieure (5) est légèrement plus importante pour permettre d'obtenir le degré de lordose qui convient.
La face antérieure comporte deux perçages destinés à la mise en place de la cage au moyen d'une tige munie de deux picots rétractables. Cette tige est représentée en figure 2.
Les faces latérales (9) et (10) sont en forme de trapèze isocèle.

Les arêtes de toutes les faces de la cage ainsi que celles de la cloison sont pourvues de crans (11), dont le profil est étudié pour qu'il réduise le risque de déplacement secondaire.

Ainsi la cage permettra, après déplacement concevable, que la fusion osseuse se fasse dans de bonnes conditions.

Par ailleurs, les propriétés amagnétiques du matériau utilisé pour la réalisation de la cage permettront de conduire des examens au scanner ou à l'IRM sans artefacts.

Ces examens sont facilités par l'existence d'un repère radiopaque incorporé verticalement au centre de la paroi médiane, qui permettra de quantifier la compression ou déplacement éventuel de la cage.

REVENDICATIONS

1) Elément de contention interne et de fusion intersomatique des vertèbres lors de discectomie caractérisé en ce qu'il se présente sous forme d'une structure rigide en forme de cage destinée à emprisonner de l'os spongieux.

2) Elément de contention interne et de fusion intersomatique des vertèbres selon la revendication 1 caractérisé en ce que la structure rigide a la forme d'un parallélépipède.

3) Elément de contention interne et de fusion intersomatique des vertèbres selon l'une quelconque des revendications 1 à 2 caractérisé en ce que les hauteurs respectives des faces antérieures (5) et postérieure (6) de la cage permettent la conservation d'une hauteur intervertébrale et d'une lordose normale.

4) Elément de contention interne et de fusion intersomatique des vertèbres selon l'une quelconque des revendications 1 à 3 caractérisé en ce que les arêtes des faces sont munies de crans.

5) Elément de contention interne et de fusion intersomatique des vertèbres selon l'une quelconque des revendications 1 à 4 caractérisé en ce que les faces latérales 9 et 10 sont en forme de trapèze isocèle.

6) Elément de contention interne et de fusion intersomatique des vertèbres selon l'une quelconque des revendications 1 à ce que la cage est réalisée en une matière polymère, résorbable ou non, telle que polyéthylène à haut poids moléculaire et amagnétique permettant les examens au scanner ou à l'IRM sans artefact.

7) Elément de contention interne et de fusion intersomatique des vertèbres selon l'une quelconque des revendications 1 à 6 caractérisé en ce que la cage comporte une cloison médiane de renfort dont les arêtes sont munies de crans.

8) Elément de contention interne et de fusion intersomatique des vertèbres selon l'une quelconque des revendications 1 à 7 caractérisé en ce que le volume d'os emprisonné permet la communication osseuse entre la vertèbre inférieure et la vertèbre supérieure.

9) Elément de contention interne et de fusion intersomatique des vertèbres selon l'une quelconque des revendications 1 à 8 caractérisé en ce qu'il comporte un marqueur radiopaque permettant de suivre dans le temps son positionnement.

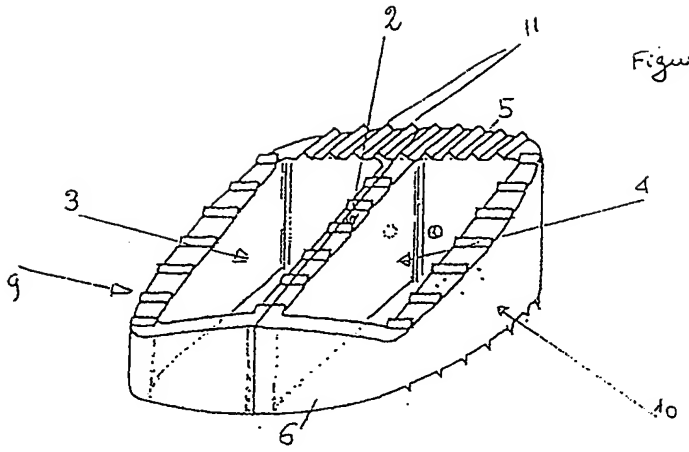

Figure 1

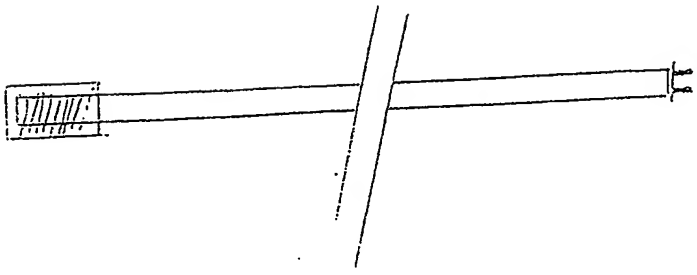

Figure 2